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Registration Decision RD2013-22

Metarhizium anisopliae strain F52

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Registration Decision for *Metarhizium anisopliae* strain F52

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Metarhizium anisopliae* strain F52 and Met52 EC Bioinsecticide, containing the technical grade active ingredient *Metarhizium anisopliae* strain F52, to reduce the numbers of whiteflies and thrips on greenhouse food crops and suppress hairy chinch bugs and ticks on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-03, *Metarhizium anisopliae strain F52*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Metarhizium anisopliae* strain F52 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-03. This decision is consistent with the proposed registration decision stated in PRD2013-03.

For more details on the information presented in this Registration Decision, please refer to PRD2013-03, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Metarhizium anisopliae* strain F52?

Metarhizium anisopliae strain F52 is a soil-dwelling fungus that infects insects and ticks and can result in death. Formulated as Met52 EC Bioinsecticide and applied as a foliar spray it reduces whitefly numbers on greenhouse tomato, reduces thrip numbers on greenhouse pepper, greenhouse strawberry and greenhouse zucchini, and suppresses hairy chinch bugs and ticks on turf. A granular formulation of *Metarhizium anisopliae* strain F52 (Met52 Granular Bioinsecticide) is currently registered for the control of black vine weevil and strawberry root weevil when applied in the growth media of container grown ornamentals. Both end-use products are Commercial Class.

Health Considerations

Can Approved Uses of *Metarhizium anisopliae* strain F52 Affect Human Health?

***Metarhizium anisopliae* strain F52 is unlikely to affect your health when Met52 EC Bioinsecticide is used according to the label directions.**

People could be exposed to *Metarhizium anisopliae* strain F52 from the application Met52 EC Bioinsecticide. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *Metarhizium anisopliae* strain F52 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure that the food Canadians eat is safe.

When *Metarhizium anisopliae* strain F52 was administered orally to rats, no signs of toxicity or disease were observed. Although *Metarhizium anisopliae* strain F52 can produce toxic metabolites, analytical data were submitted showing that these were not detected in the technical grade active ingredient. Furthermore, the growth of *Metarhizium anisopliae* strain F52 on insect hosts is unlikely to result in residues of metabolic byproducts occurring on food commodities. Therefore, the establishment of an MRL is not required for *Metarhizium anisopliae* strain F52. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling Met52 EC Bioinsecticide

Occupational risks are not of concern when Met52 EC Bioinsecticide is used according to label directions, which include protective measures.

Occupational risks are not of concern when Met52 EC Bioinsecticide is used according to label directions, which include protective measures.

Workers handling Met52 EC Bioinsecticide can come into direct contact with *Metarhizium anisopliae* strain F52 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers exposed to the end-use product must wear waterproof gloves, long-sleeved shirts, long pants, eye goggles, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Met52 EC Bioinsecticide Is Introduced Into the Environment?

Environmental risks are not of concern.

Metarhizium anisopliae strain F52 is a non-indigenous soil microorganism that is pathogenic to specific host insects. Since the reproduction of conidiospores is dependent upon infection of a suitable host under conditions of high humidity, the proliferation of *Metarhizium anisopliae* strain F52 in the environment would be limited. It is likely that levels of *Metarhizium anisopliae* strain F52 would return to levels comparable to native populations of *Metarhizium anisopliae* after application of Met52 EC Bioinsecticide.

Toxicity testing on non-target organisms shows that *Metarhizium anisopliae* strain F52 is capable of causing some adverse effects to certain aquatic organisms when exposed to high concentrations. However, the end-use product label includes instructions for applicators to control spray drift; therefore, the application of Met52 EC Bioinsecticide onto turfgrass and vegetable crops in greenhouses is unlikely to result in significant contamination of aquatic environments. Therefore, the risk to aquatic organisms from the use of Met52 EC Bioinsecticide is low. Toxicity testing also shows that terrestrial non-target organisms, other than target insect species, were not adversely affected by *Metarhizium anisopliae* strain F52 when exposed to high concentrations.

Value Considerations

What Is the Value of Met52 EC Bioinsecticide?

Applied as a foliar spray, Met52 EC Bioinsecticide reduces whitefly numbers on greenhouse tomato, reduces thrip numbers on greenhouse pepper, greenhouse strawberry and greenhouse zucchini, and suppresses hairy chinch bugs and ticks on turf.

Met52 EC Bioinsecticide is for use against whiteflies and thrips on greenhouse food crops, hairy chinch bugs and ticks on turf. Whiteflies and thrips are serious pests of greenhouse food crops. Chinch bugs can be serious pests of turf grass. Most pest control products for these uses are conventional chemical insecticides. Few pest control products are registered for use against ticks in turf.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Met52 EC Bioinsecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed to large quantities of Met52 EC Bioinsecticide, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since the end-use product has been identified as a sensitizer. Therefore, anyone handling or applying Met52 EC Bioinsecticide must wear waterproof gloves, long-sleeved shirts, long pants, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Due to the irritation potential identified for Met52 EC Bioinsecticide, workers and handlers are also required to wear eye goggles. Also, the signal words, "POTENTIAL SENSITIZER", "WARNING – EYE IRRITANT" and "CAUTION – SKIN IRRITANT" must appear on the principal display panel, and precautionary statements, "DO NOT get in eyes. Avoid contact with skin." and "May cause sensitization." are required on the secondary display panel of the label.

Environment

The end-use product label will include standard environmental precaution statements that prevent the contamination of aquatic systems from the use of Met52 EC Bioinsecticide.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-03) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

No comments were received.